

K101962

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510(k) SUMMARY

Submitter Information

Submitter's Name: OrthoHelix Surgical Designs, Inc.
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Medina, Ohio 44256
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Prepared By: Brian Hockett, Elizabeth Altenau
Contact Person: Derek Lewis
Date Prepared: 7/12/10

SEP 27 2010

Device Information

Trade Name: Mini MaxLock Extreme® Plating System

Common Name: Fixation Plate

Classification Name: Plate, Fixation, Bone

Device Classification: Single/multiple component metallic bone fixation appliances (Class II per 21 CFR 888.3030)
Panel: Orthopedic, Product Code: HRS
Smooth or threaded metallic bone fixation fastener (Class II per 21 CFR 888.3040)
Panel: Orthopedic, Product Code: HWC

Predicate Device: The Mini MaxLock Extreme® Plating System is equivalent to current legally marketed devices.

Material Composition: Titanium Alloy

Device Description: The Mini MaxLock Extreme® Plating System consists of various size plates and screws used to stabilize and aid in the fusion or repair of fractured small bones and bone fragments. The plates are offered in different lengths and sizes. The screws are offered in different diameters and lengths. All implantable components are manufactured from implant grade titanium alloy.

Intended Use: The Mini MaxLock Extreme® Plating System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments.

Substantial Equivalence: The Mini MaxLock Extreme® Plating System is substantially equivalent to the Synthes Modular Mini Fragment LCP System (K063049), the Small Bone Innovations Hand Fracture System (K050462), the DePuy Orthopedic Small Bone Locking Plate System (K083364), and the OrthoHelix Modular Foot System (K073624). Static mechanical testing and calculations comparing the bending and torsional strength of the subject and predicate devices were performed and the results support substantial equivalence. Due to similarities in indications, design, materials, and superior static testing performance, fatigue testing was not required. No new issues of safety and effectiveness have been raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OrthoHelix Surgical Designs, Inc.
% Mr. Derek Lewis
1065 Medina Road, Suite 500
Medina, Ohio 44256

SEP 27 2010

Re: K101962

Trade/Device Name: Mini MaxLock Extreme® Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: September 13, 2010

Received: September 15, 2010

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

*for Peter D. Runyan MD MPH
DEP DIR*

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K101962
SEP 27 2010

510(k) Number (if known): K101962

Device Name: Mini MaxLock Extreme® Plating System

Indications for Use:

The Mini MaxLock Extreme® Plating System is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments.

Prescription Use X

AND/OR

Over-The-Counter-Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Jonathan J. for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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